REMARKS

The remainder of this Amendment is set forth under the appropriate subheading for the convenience of the Examiner.

I. Indication of Allowable Subject Matter

Applicants respectfully express appreciation to the Office for the indication of allowable subject matter concerning Claim 31. Applicants respectfully disagree with the remainder of the rejections. Applicants believe that Claims 1-30, and 32 are patentable over the cited references. Applicants are, thus, arguing the instant rejection. Applicants reserve the right to place the remaining dependent claims or a portion of the dependent claims as being dependent on Claim 31 at a later date and filing the instant rejected claims in a continuation patent application in order to advance the prosecution of this matter.

II. Claim Status

The instant patent application includes thirty-two (32) pending claims. Claims 1, 12, 19, 24, 25 and Claim 31 will be the independent claims after entry of the instant amendment. Claims 2 through 11 and Claims 26 through 28 depend from Claim 1. Claims 13 through 18 depend from independent Claim 12. Claims 20 through 23, and Claims 29, 30, and 32 depend from Claim 19.

Applicants have amended Claims 1 through 4, 6 through 13, 15, 19, 20, 21 and 23 through 32. Specifically, Claims 1-3, 12-13, 15, 19, 20-21, 23, 25-28 and 30-32 are amended to now recite that an impedance of "an ankle joint" is modulated throughout a walking cycle from modulating an impedance of an "orthotic joint." Support for the instant claim amendment can be found at various locations of the Applicants' specification, such as, for example, in Figure 1, and at page 5, lines 5-7, which describe an orthosis of the invention that fits over a person's foot, at page 9, lines 5-20, and at other locations. Applicants also amend Claims 3, 15, 23, 28, and 31 to recite that the impedance is controlled by joint stiffness, damping, or both to achieve a spring-damper positional control. Applicants have corrected the incorrect term of "spring damping" from the claims to the correct term of "damping." Support for the instant claim amendment can

be found at various locations of the Applicants' specification, such as, for example, at page 9, line 18, and at other locations.

Applicants have also amended Claims 4-11 to correct the antecedent basis of the claims from "the orthosis" to "an orthosis," and to correct other minor matters of form. Independent Claim 12 has been amended to remove the phrase "orthosis leg portion and the orthosis foot portion defining an orthotic joint." Applicants have further amended Claim 24 to recite that ankle stiffness is modulated during a "stance period." Support for the instant claim amendment can be found at various locations of the Applicants' specification, such as, for example, at page 14, lines 17-24 and at other locations.

III. Rejection of Claims 1, 2, 4, 10, 11, 19, 20, 22 and 29-30 under 35 U.S.C. §102(b)

a. The Rejection and a Discussion of the Examiner's Comments.

Claims 1, 2, 4, 10, 11, 19, 20, 22 and 29-30 are rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,112,296 to Beard *et al.* (hereinafter "Beard *et al.*").

In response to Applicants' arguments made on December 19, 2006, the Office at page 7 of the Action states that:

> "with regard to the rejection of claims 1-5, 10-15, 18-22, and 23 under 35 U.S.C. §102(b) as anticipated by Beard '296 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of the previously applied art..."

Specifically, the Office now contends at page 2 of the Action that:

> "Beard et al. discloses a variable-impedance active ankle foot orthosis (title: abstract; column 3, lines 5-40; column 4, lines 20-25; column 5, lines 50-60) comprising an actuator coupled to a foot portion of the orthosis (FIG. 1, actuator 10; column 4, lines 1-5 and 25-30; column 5, lines 1-48) for modulating an impedance of an orthotic joint throughout a walking cycle for treating an ankle foot gait pathology, wherein the pathology comprises a drop foot (abstract; column 5, lines 38-60)."

The Office continues to state at page 2 of the Action that:

> "[i]t is noted that there is inherently a joint formed between the leg portion 4 and the foot portion 2. Alternatively, the knee orthotic joint 8 can be considered to anticipate the claims as written, since it is not specified that the joint be the ankle joint, but rather that the joint be related to treatment of an ankle foot gait pathology."

Applicants note that the Examiner initially states at page 7 of the Action that Applicants' previous arguments were considered and found to be persuasive, and the rejection was withdrawn, however, the Office then continues to assert virtually the exact same rejection at page 2. If the application is not deemed in condition for allowance after entry of the above Amendment and Remarks, Applicants respectfully invite the Examiner to conduct an Examiner's Interview to further discuss the patentable feature of the claims, and to discuss the rejections.

The Office states that Beard *et al.* teaches a variable-impedance active ankle foot orthosis at Column 3, lines 5-40; Column 4, lines 20-25 and Column 5, lines 50-60.

b. Discussion of the Subject Matter of Beard *et al.*

Beard *et al.* disclose a biofeedback activated orthosis configured for foot-drop rehabilitation. The orthosis includes foot brace 2 secured to the foot of the user that includes lifting cable 3 for lifting foot 54 throughout a gait cycle. (See Column 4, lines 40 through 43). Beard *et al.* also disclose a device 8 for sending a signal to a controller to represent an angular relationship between the lower leg and the thigh. (See Column 4, lines 60 through Column 5, line 3). If both muscle activity parameters and the angular relationship parameters between the lower leg and the thigh are met, then a processing signal is sent to activate geared motor 29 to timely apply tension to the cable and to pull upwardly foot brace 2. (See Column 5, lines 48 through 58).

c. Discussion of the Subject Matter of Applicants' Claims

Applicants claim a variable-impedance active ankle foot orthosis device. In one embodiment, the device includes an actuator and a spring. The spring is linked to the actuator. The actuator modulates or selectively varies an impedance of the ankle joint by controlling the spring. This modulation is not disclosed or suggested by Beard *et al.*

One embodiment of the claimed invention is described at pages 4 through 5 and FIG. 1, which discloses that the actuator 12 includes a brushless DC motor operatively connected in series with a spring. The actuator provides force control by controlling the extent that the spring

is compressed. In another embodiment, the orthosis device further includes sensors 14 and 16, or more particularly, a ground reaction sensor and an ankle angle sensor to provide feedback to the actuator, which then modulates an impedance of an ankle joint by controlling the spring.

d. Deficiencies in Beard et al.

Beard *et al.*'s device is not a variable-impedance active ankle orthosis. The Examiner's cited passages do not disclose or suggest any variable-impedance active ankle orthosis. The Beard *et al.* device simply does not modulate the impedance of the ankle joint.

Secondly, the Examiner's assertion that this variable impedance is inherent in the "joint" between the leg portion 4 and the foot portion 2 is erroneous since there is no joint between the leg portion 4 and the foot portion 2. Moreover, Applicants' system selectively varies, or selectively changes the impedance of an ankle joint, while Beard *et al.* simply uses feedback to activate the motor and to pull the cable 3, and to pull upwardly the foot brace 2.

Thirdly, if it is the Examiner's assertion that the impedance of the ankle joint of the individual is what is being modulated, this too is also erroneous. Applicants contend that the impedance of the ankle joint between the leg and the foot (when the individual is wearing the Beard *et al.* device) is the same throughout the walking cycle and is not modified or varied. The cable 3 of Beard *et al.* simply lifts the foot 54 throughout a walking or gait cycle.

Moreover, simply because the cable 3 lifts the foot 54 throughout a gait cycle does not mean that the impedance of the ankle joint is varied or modulated, let alone actively and throughout the walking cycle. This varying impedance throughout a walking cycle is especially advantageous since Applicants' device can vary impedance quickly in response to gait speed of the individual. See Applicants specification at page 8, lines 19-28. Applicants respectfully submit that the individual's ankle joint wearing the Beard *et al.* device has the same impedance regardless of whether the foot is being lifted by the cable 3 or not.

The Examiner is mistaken by equating merely lifting the foot with Applicant's device for modulating or selectively changing an impedance of the ankle joint throughout a walking cycle for treating an ankle foot gait pathology. The Beard *et al.* device does nothing to change the impedance of the ankle joint, and simply provides a tensile force to the foot about the foot portion.

Fourthly, the Office assertion that the knee joint is considered to anticipate the claims is also erroneous at page 2, since again the impedance of the knee joint is unchanged by the Beard et al. device. At most, Beard *et al.* discloses that a backlash inhibiting device 67 prevents backlash of cable 3 by maintaining a minimum amount of tension in cable 3 at all times. Beard *et al.* does not modulate any impedance of the ankle joint nor is an ankle joint selectively controlled as presently claimed in independent Claim 1.

Reconsideration and withdrawal of the rejection of Claim 1 are requested. Claims 2, 4, 10, and 11 depend from Claim 1 and are patentable as these claims depend from an allowable base claim. Claim 19 is patentable for reasons similar to those argued above for Claim 1. Claims 20, 22, 29, and 30 are also patentable as these claims depend from independent Claim 19.

IV. Rejection of Claim 24 under 35 U.S.C. §102(b)

Claim 24 is rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,643,332 to Stein (hereinafter "Stein"). In the alternative, Claim 24 is also rejected under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 6,507,757 to Swain *et al.* (hereinafter "Swain *et al.*"). The Examiner stated that, "Stein '322 clearly outlines a FES stimulation device and method which modulates ankle stiffness during the swing phase of a walking cycle, which inherently provides control during the controlled plantar flexion and minimizes forefoot collision[s]". See Page 4 of the Action.

Claim 24 provides applying electrical pulses to elicit muscle contractions to actively modulate ankle stiffness, and to achieve a torsional spring control during the stance period of walking. Stein teaches an electrical stimulation device which causes a depolarization of the underlying membrane, and which causes propagation of an impulse along the nerve and contraction of the muscle. Swain discloses an electrical stimulator for attachment to a leg. The stimulator includes electrodes for attachment to the leg to apply an electrical stimulus. The stimulator also includes a foot switch for sensing foot rise or foot strike. A circuit is responsive to the foot switch and generates stimulation pulses in response to the rise or strike. Stein and Swain *et al.* do not disclose or suggest modulating the joint stiffness, nor damping, as claimed. The method of Claim 24 is novel under 35 U.S.C. §102(b) and, therefore, reconsideration and withdrawal of this rejection are respectfully requested.

V. Rejection of Claims 1-9, 11-23, 25-29, and 32 under 35 U.S.C. §102(b)

Claims 1-9, 11-23, 25-29, and 32 are rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,662,693 to Johnson *et al.* (hereinafter "Johnson"). The Examiner stated that particular emphasis is placed on the abstract, Figures 1, 3c, 5 and 9; and column 8, lines 4-14; column 9, lines 3-27; and column 10, lines 55-65.

Johnson discloses an exoskeleton that is capable of providing a normal person with additional strength and support thereby creating a state of super mobility. See Column 6, lines 53-59. The exoskeleton includes an apparatus that includes braces that reinforce four segments of the patients legs. In one embodiment, the person may have a mobility impairment below the ankle, the knee or the upper thigh. See Column 6, lines 60-67. These braces cover the entire leg and is not an active ankle foot orthosis.

The braces includes pneumatic actuators to allow for various force states of the brace. The actuators provide contractile forces about a joint 113 creating and sustaining torque required for mobility enhancement or stability. See Column 7, lines 26-35.

Column 8, lines 5-34 disclose that in a human ankle joint contractile forces that are associated with the ankle joint include a large force in the foot plantation movement and a relatively smaller toe lift force. Johnson discloses that a spring can be provided to substitute for an opposing muscle in a lopsided torque requirement to balance forces between the foot plantation movement and the toe lift.

Column 8, lines 15-25 of Johnson discloses that integration of goniometric inputs from the fingers, control actuators, and sensors make the active orthosis function as a functioning mobility assist device. However, Johnson does not disclose or suggest a device for modulating an impedance of an ankle joint throughout a walking cycle for treating an ankle foot gait pathology. In contrast, Johnson discloses a exoskeleton that provides the forces necessary for the walking cycle. See Column 2, lines 5-28.

Johnson does not disclose or suggest modulating an impedance of the ankle joint throughout a walking cycle, but instead discloses providing contractive forces to joints associated with the exoskeleton to provide mobility. Johnson discloses that the patient using the brace can set the amount of stiffness of the legs for any force or load. This provides that the legs wearing the brace can be self stable. This is not the same as modulating an impedance of the ankle joint throughout a walking cycle for treating an ankle foot gait pathology.

Claim 1 is novel under 35 U.S.C. §102(b) and, therefore, reconsideration and withdrawal of this rejection are respectfully requested. Claims 2 through 9, 11, and 26-28 depend from Claim 1 and are patentable for at least the reasons discussed above for Claim 1. Independent Claims 12, and 19 are also patentable for at least the same reasons discussed above for Claim 1. Claims 13-18 depend from Claim 12 and are patentable for at least the same reasons discussed above for Claim 12. Claims 20-23, 29-30, and 32 depend from Claim 19 and are patentable for at least the same reasons discussed above for Claim 19.

VI. Rejection of Claims 1-4, 6-8, 11-23, 25-30 and 32 under 35 U.S.C. §102(e)

Claims 1-4, 6-8, 11-23, 25-30, and 32 are rejected under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 6,966,882 to Horst *et al.* (hereinafter "Horst"). The Examiner stated on page 4 of the Action that particular emphasis is placed on the abstract, Figures 1, 4, and 6, and related paragraphs.

Horst discloses a brace device which is attached at the knee. The structural frame of the device includes a pair of hinges 18 at the medial and lateral sides of the brace. See Column 5, lines 1-15. The brace device also includes an actuator 12 that is coupled to the brace to provide the force needed to assist or resist the leg muscle during rotation. The actuator 12 includes a rotary motor. The rotary motor has a center of rotation which is located close to a center of rotation of the knee joint. See Column 7, lines 28-44. Horst does not disclose or suggest a device for modulating an impedance of an ankle joint throughout a walking cycle for treating an ankle foot gait pathology. In contrast, Horst discloses a brace device for rotating a knee joint to assist or resist (for exercise) a primary movement direction of the leg muscle. See Column 7, lines 18-26. At most, Horst does disclose that the device may be use to assist with rotation of an ankle joint at Column 7, line 25. However, Horst does not disclose or suggest modulating an impedance of the ankle joint throughout a walking cycle for treating an ankle foot gait pathology. In contrast, Horst discloses providing a rotating force to a portion of a brace located at the knee joint using a number of sensors. This is not modulating an impedance of the ankle joint throughout a walking cycle, and Claim 1 is novel under 35 U.S.C. §102(e). Reconsideration and withdrawal of this rejection are respectfully requested. Claims 2 through 4, 6-11, and 26-28 depend from Claim 1 and are patentable for at least the reasons discussed above for Claim 1.

Independent Claims 12, 19, and 25 are also patentable for at least the same reasons discussed above for Claim 1. Claims 13-18 depend from Claim 12 and are patentable for at least the same reasons discussed above for Claim 12. Claims 20-23, 29-30, and 32 depend from Claim 19 and are patentable for at least the same reasons discussed above for Claim 19.

VII. Rejections of Claims 6 through 8 under 35 U.S.C. §103(a)

Claims 6-8 disclose a variable impedance active ankle foot orthosis that has a device for modulating an impedance of an ankle joint throughout a walking cycle for treating a foot pathology. The orthosis can include sensors, such as an ankle angle sensor, one or more ground reaction force sensors, an actuator or controller for controlling the orthosis.

The Office rejects Claims 6 through 8 under 35 U.S.C. §103(a) in view of Beard *et al.* The Office states at page 5 of the Action that Beard *et al.* disclose an angle sensor capable of use with the ankle. The Examiner continues that since a knee angle inherently has a correlated and consistent ankle angle during the standing phase, measuring that the angle of the knee is synonymous with measuring the corrected ankle angle. The Examiner also stated that angle sensors are well known in the art. The Examiner stated that it would have been obvious to modify the system taught by Beard *et al.* with the devices described by the surrounding references. Claims 6 through 8 depend from independent Claim 1.

As discussed above, there is no disclosure or suggestion in Beard *et al.* of Applicants' claimed variable impedance action ankle foot orthosis, wherein a spring linked to an actuator is controlled to modulate an impedance of the orthotic joint. Beard *et al.* simply discloses timely lifting the forefoot with a cable. Applicants submit that the impedance of the ankle joint is unchanged during the lifting, and the orthosis of Beard et al. does not include an inherent joint between the orthosis shin portion and the forefoot portion. The Stein and Horst patents do not remedy these deficiencies. Beard *et al.* does not recognize the problem in that by modulating impedance as claimed the patient can vary gait speed and the orthosis can quickly adapt to a different gait speed, which is not recognized by Beard *et al.* Applicants refer the Examiner to page 8, lines 19-28 of the Applicants' patent application as originally filed. This is not an obvious solution, and not a predictable variation of Beard *et al.* Applicants system is superior to the Beard *et al.* system. The subject matter of Applicants' invention of Claims 1 and 12 meet the

criteria under 103(a) in view of Beard *et al.* Therefore, the subject matter of dependent Claims 6 through 8 is patentable.

VIII. Rejection of Claim 9 under 35 U.S.C. §103(a)

Claim 9 is rejected under 35 U.S.C. §103(a) as being unpatentable over Beard *et al.* in view of U.S. Patent No. 6,507,757 to Swain *et al.* and in further in view of Naft *et al.* The Examiner stated that it would have been obvious to one of ordinary skill in the art to modify the system of Beard *et al.* with the foot switch of Swain *et al.*, or Naft *et al.* to provide the Beard *et al.* system with the same advantage of improving patient gait and treating foot drop.

Naft *et al.* further discloses a selectively lockable orthotic knee joint that includes a pressure sensor. The orthotic knee joint includes a spring washer that biases a first ratchet plate 50 from a second ratchet plate 38. Swain *et al.* discloses a stimulator device for electrical stimulation of the leg. Swain *et al.* discloses controlling stimulation pulses to muscle groups during dropped foot and other patient conditions (See Column 12, lines 16-65).

Neither Swain *et al.* nor Naft *et al.* cure the deficiencies of the primary reference or disclose or suggest a device for modulating an impedance of an orthotic joint throughout a walking cycle for treating an ankle foot gait pathology. Applicants' orthosis is advantageous in that it can rapidly modulate the impedance of the ankle joint based on the gait speed of the patient, which is not disclosed or suggested by Beard *et al.* Beard *et al.* does not recognize this problem. In one embodiment, the Applicants' device has a spring linked to an actuator with the actuator modulating an impedance of an orthotic joint by controlling the spring. Applicants submit that the impedance of the ankle joint of Beard *et al.* is unchanged, and not modulated. The cited references don't cure the deficiencies of Beard *et al.* Naft *et al.* does not disclose or suggest any device modulating an impedance of an ankle joint as presently claimed in Claim 1.

CONCLUSION

In view of the above amendments and remarks, it is believed that all of the pending Claims (1-32) are in condition for allowance. It is respectfully requested that all of the outstanding rejections be reconsidered and withdrawn, and that the application be passed to

issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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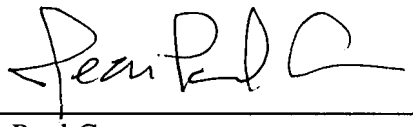
By 

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